

NATIONAL INSTITUTES OF HEALTH

Tribal Consultation Report
on the
Draft NIH Tribal Consultation Policy

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Organization of Report

This report summarizes the input and written testimony NIH received through Tribal Consultation and provides the agency's responses. It includes an executive summary, background, Consultation session details, Tribal input with NIH responses, and topical themes from Tribal-serving organizations.

Executive Summary

In FY 2021, the National Institutes of Health (NIH) initiated formal Tribal Consultation on the draft NIH Tribal Consultation Policy. Prior to this, the agency adhered to the [2014 NIH Guidance on the Implementation of the HHS Tribal Consultation Policy](#). The draft NIH Policy, developed with extensive input from the NIH Tribal Advisory Committee (TAC) and the NIH Office of Science Policy (OSP), focused on NIH-specific issues. It was designed to ensure a standard and transparent process for all NIH Institutes, Centers, and Offices (ICOs) to follow when conducting Consultation with Federally recognized Indian Tribes.

NIH conducted its Consultation as part of the U.S. Department of Health and Human Services (HHS) Regional Tribal Consultation Sessions, held May through August 2021. NIH also received written testimony from Tribal Nations. Overarching themes included the following: Tribal Sovereignty Over Research; Importance of Tribal Consultation; Tribal Consultations and Presidential Executive Orders; Reporting Consultation Outcomes; Recognizing the Diversity of Tribal Nations; and Continued Tribal Nation Engagement. Specific recommendations were also made to include sections noting definitions, objectives, and roles and responsibilities.

Background

The U.S. has a unique legal and political relationship with American Indian and Alaska Native (AI/AN) Tribes as set forth in the U.S. Constitution and given substance by numerous treaties, statutes, Executive Orders, and court decisions. The HHS Tribal Consultation Policy states that before any HHS action is taken that will significantly affect Indian Tribes, Consultation with Indian Tribes will occur to the extent practicable and permitted by law. The HHS Tribal Consultation Policy also requires each HHS Operating and Staff Division to have an accountable process for ensuring meaningful and timely input. In 2014, NIH released the *NIH Guidance on the Implementation of the HHS Tribal Consultation Policy*, and since then has conducted numerous consultations.

NIH is committed to respecting Tribal sovereignty and self-government. Given the complexity of NIH's structure with its 27 Institutes and Centers and a research portfolio of more than \$40 billion, the agency undertook Tribal Consultation for feedback and perspective on its draft Tribal Consultation Policy, an important step to a new and well-considered NIH Tribal Consultation Policy that would standardize the NIH process for initiating Consultation to seek Tribal input on proposed and ongoing NIH policies, programs, and research activities. The draft

Policy was written with extensive input from the NIH Tribal Advisory Committee and the Office of Science Policy. The draft Policy established a set of requirements and expectations for NIH and outlined a process to identify Critical Events which would initiate Consultation. The Policy holds all levels of management within the NIH responsible for effectively implementing Tribal Consultation.

In addition, the Policy reaffirms and strengthens the government-to-government relationship between Tribal Nations and the Federal Government. NIH strives to include AI/AN populations in biomedical and behavioral research to inform efforts at raising the overall health of Tribal communities, to help develop a cadre of AI/AN researchers, and to build the research capacity of Tribal Nations. This can only be done through effective Tribal Consultation.

Consultation Session Details

NIH initiated formal Tribal Consultation on May 7, 2021 with a 'Dear Tribal Leader Letter' and a 'Framing Letter' indicating that the NIH Consultation would be held in conjunction with the HHS Regional Tribal Consultation Sessions held May through August 2021.

At each of the HHS Regional Tribal Consultation Sessions, NIH leadership presented an overview of the NIH mission and organization; the role of the NIH Tribal Health Research Office; and the agency's investment in research focused on AI/AN health.

Next, NIH's approach to Tribal Consultation was discussed and key elements that the agency wanted input on were noted. NIH sought guidance on how to identify Critical Events; which NIH policies, programs, and research projects had substantial impact on Tribes; best ways to brief Consultation participants; how to effectively capture input; and appropriate timelines for reporting on NIH decisions or responses. NIH also encouraged the submission of written testimony, comments, or questions by August 31, 2021.

During the sessions, NIH shared its internal process for considering all feedback received through Consultation. Input would be reviewed with the NIH OSP and the NIH Branch of the HHS Office of the General Counsel. The HHS Office of the General Counsel and the Assistant Secretary for Legislation would then conduct the final review and approval. Next, the Policy would be presented to NIH systematically through Institute and Center Directors and multiple committees with representatives from across NIH. Once officially effective, the Policy would be implemented by ensuring all NIH components have the resources and training necessary to fulfill its requirements.

Tribal Input and NIH Responses

NIH reviewed all input and written testimony received from Tribal leaders during the NIH 2021 Tribal Consultation and summarized recommendations by themes grouped under two sections: general comments and comments specific to the wording of the Policy itself.

General Comments

Tribal Sovereignty Over Research – Tribal leaders stated that the Consultation Policy was important to reinforce Tribal sovereignty over research and emphasized that data sovereignty is part of Tribal sovereignty. Tribal Nations have the right to determine how research is conducted and to exert control over the data collected.

NIH Response: NIH respects Tribal sovereignty and recognizes the unique relationship between the Federal government and Tribal Nations. The purpose of the NIH Tribal Consultation Policy is to establish an effective, meaningful, and transparent process followed by all NIH entities when engaging in Consultation. The Policy does not specifically address data, but states that before any action is taken that will significantly affect Indian Tribes, NIH will undertake Consultation.

In 2019, NIH initiated a [Tribal Consultation](#) on a new policy proposal for the management and sharing of data resulting from NIH-funded or conducted research. Following recommendations received, NIH intends to emphasize the role of Tribal sovereignty in a future data management and sharing policy. To supplement that policy, NIH intends to develop and disseminate guidance that promotes research partnerships between researchers, Tribal Nations, and urban AI/AN communities and helps researchers respectfully manage and share data.

Importance of Tribal Consultation – Tribal leaders stressed the need for meaningful research partnerships based on open communication, trust, and reciprocity between researchers and Tribal communities. Tribal leaders requested NIH improve the way it interacts with Tribes. Specifically, NIH was asked to ensure that Tribes are ethically and meaningfully included in research. Research should be tailored to communities in a way that benefits them and has substantial impact.

NIH Response: NIH appreciates that building meaningful partnerships with Tribal Nations requires an ongoing, sustained effort. NIH is committed to better promote an authentic, inclusive, and equitable partnership with American Indian and Alaska Native communities by improving cultural awareness and respect across NIH and its intramural and extramural research programs.

Tribal Consultations and Presidential Executive Orders – Tribal leaders emphasized that Consultations are supported by Executive Orders and that all agency policies on Tribal Consultation should mirror the HHS Policy. If agencies create their own policies, it can cause conflict.

NIH Response: NIH appreciates Tribal leaders pointing out the need for consistent policies and practices across the HHS Operating Divisions. The draft NIH Tribal Consultation Policy is intended to complement the HHS Tribal Consultation Policy by focusing on NIH specific issues. It will also include details about the process and expectations so that all NIH Institutes, Centers, and Offices will follow a standard process when conducting Consultation. The Policy will be reviewed again by NIH, the TAC, the NIH Office of Science Policy, and the Office of the General Counsel to ensure it aligns with HHS Policy.

Reporting Consultation Outcomes – Tribal leaders indicated that they sometimes hear feedback from Consultation, but also want to be ‘at the table’ to help formulate changes. Once input has been given Tribal leaders want to see that input reflected verbatim, if possible, in a report so they know their message was received. It was also noted that Tribal leaders want to know how their input has informed practices or policy development.

Tribal leaders recommended that the Policy require an annual report which should include: a description of the issue/subject, details on the process followed, recommendations by Tribal leaders, a list of follow-up actions, a proposed timeline to address these issues, and a discussion of Tribal satisfaction with the Consultation process.

NIH Response: NIH appreciates the suggestion to add an annual reporting requirement to the Policy. NIH provides HHS information on its Consultations for inclusion in the HHS Annual Tribal Consultation Report. To ensure timely follow up from Consultation, NIH will add a requirement that within 90 days of the conclusion of each Consultation, NIH will publish a Consultation Report. The report will describe themes and recommendations heard throughout the Consultation and any NIH plans in response. At a minimum, the report will include the following:

- Description of the Critical Event and the steps taken to initiate a Consultation
- Summary of the Consultation process
- Summary of the concerns and perspectives raised, or recommendations provided by Indian Tribes during the Consultation process
- NIH’s responses to stated concerns and/or recommendations with a description of any steps to adopt measures or changes recommended by Indian Tribes
- Proposed timelines for addressing input provided by Indian Tribes during the Consultation process

The new Policy will also address evaluation of the Consultation process itself. NIH will seek Tribal feedback to help assess implementation and effectiveness of this Policy and whether amendments are needed.

Recognizing the Diversity of Tribal Nations – Tribal leaders stated that Tribes had different cultures and government structures. For instance, Pueblo Tribal leadership can change annually, so the Consultation process may begin in one leader’s term and then cross over into another leader’s term. Tribal leaders stressed the need to take this into account when planning. Listening sessions would also be another way to expand outreach.

NIH Response: To the extent possible, NIH will accommodate timing considerations for the situations identified. However, there may be times when NIH needs to convene meetings on short notice or at potentially inconvenient times with the affected, or potentially affected AI/AN Tribe(s), to discuss the Critical Event on which Tribal Consultation is sought. For instance, the rapid-response NIH Tribal Consultation on COVID-19 Research was held in May 2020 to seek input from Tribes about ways NIH could support time-sensitive research that will provide vital information to help address the COVID-19 pandemic in Tribal communities.

Consultation mechanisms may include one or more activities including: face-to-face meetings, virtual meetings, teleconferences, webinars, and correspondence. Additionally, Tribes will be given the opportunity to provide written input throughout the Consultation period indicated on the ‘Dear Tribal Leader Letter’ and/or additional notification, usually within 30 to 60 days after the conclusion of the Consultation.

Continued Tribal Nation Engagement – Tribal leaders noted that the NIH Tribal Consultation Policy was important, but also required ongoing conversations with Tribes about research issues such as informed consent, protecting data, and obtaining Tribal consent for publications, and oversight by Tribal Institutional Review Boards. Tribal leaders emphasized that research include American Indians and Alaska Natives to advance equity and improve health.

NIH Response: This Policy reflects NIH’s commitment to Tribal Nations. Enhancing communication and collaboration is vital to building relationships based on trust and integrity. The NIH seeks to promote and strengthen communication and collaboration between the NIH and Tribal communities. NIH seeks to expand scientific knowledge to improve the health of American Indian and Alaska Native communities, as well as to develop research that will be accepted by and useful to these communities.

Comments Specific to the Wording of the Policy

Include Definitions in Policy – Tribal leaders commented that NIH should develop a definition section after Section 1 that includes a definition of Consultation that is consistent with the Centers for Medicare and Medicaid Services’ Tribal Consultation Policy.

NIH Response: NIH will include a definition of Consultation in the appropriate section adhering to the HHS Tribal Consultation Policy language. The following definition will be added: “An enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process, which results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues.”

Specify Policy Objectives – Tribal Leaders requested that the Policy include an ‘Objectives’ section addressing the following: minimum requirements and expectations; identification of critical events; improvement of communication channels among Tribes and Tribal serving organizations and the TAC; coordination with the Indian Health Service and other HHS Operating Divisions; requirement that all levels of NIH management are responsible for implementing the Policy; definition of roles and responsibilities; and annual reporting.

NIH Response: NIH will adjust the Draft NIH Tribal Consultation Policy to include an ‘objectives’ section as follows:

- A. To standardize the NIH process for initiating Consultation and seeking participation by Tribal Representatives in ongoing, proposed, and current policies, programs, and research activities that impact Indian Tribes.
- B. To establish a minimum set of requirements and expectations with respect to Consultation and participation for NIH and its ICOs.
- C. To establish a process for identifying Critical Events and initiating Consultation by NIH.
- D. To identify Critical Events where partnerships and the inclusion of Indian organizations would complement Consultation with Indian Tribes.
- E. To promote and develop innovative Consultation methods with Indian Tribes in the development of NIH policy.
- F. To coordinate with the HHS Divisions/Regional Offices, State agencies, and others as needed to assist Indian Tribes to communicate their priorities through biomedical research.
- G. To charge and hold responsible all levels of management within the NIH for the implementation of this Policy.

Roles and Responsibilities – Tribal leaders commented that the Policy should include a role and responsibilities section that, at a minimum, defines the roles of THRO and the TAC. NIH was also encouraged to convene a working group of the TAC to review comments and recommendations to the Policy.

NIH Response: The Policy will specifically define the role of THRO and the TAC in the Consultation process. NIH appreciates the invaluable advice of the TAC in the development of relevant NIH policies, programs, and priorities. The TAC thus supports, but does not supplant, other government-to-government Consultation activities that the NIH undertakes.

TAC has worked consistently with THRO and the NIH OSP to develop the draft NIH Tribal Consultation Policy and has played an important role identifying Critical Events, including the topics of past NIH Tribal Consultations on Opioids in Indian Country and COVID-19 Research. After Consultation concludes, THRO will share Tribal input with the Committee and request additional review.

Additional Input from Tribal-serving Organizations

NIH also received written comments from Tribal-serving organizations, which do not have sovereign status as Tribal Nations. As such, their comments were considered and categorized separately. Comments focused on the following areas: upholding Tribal sovereignty and strengthening the government-to-government relationship; conducting Consultation in a standard and timely manner with advance notice; adding an objectives section to the Policy; defining the roles of the THRO and TAC in Consultation; and reporting Consultation outcomes.

Closing

NIH thanks Tribal leaders for their time and invaluable recommendations to the development of the agency's Consultation policy. NIH is committed to building strong relationships with Tribal Nations and is grateful for the incredible efforts of Tribal leaders and members, researchers, and policy makers who advocate for Tribal Nations to guide biomedical and behavioral research on behalf of their people.